

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**Allergenic Products Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Allergenic Products Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on March 15, 2002, from 8 a.m. to 4:15 p.m.

*Location:* Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

*Contact Person:* William Freas or Pearlline Muckelvene, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

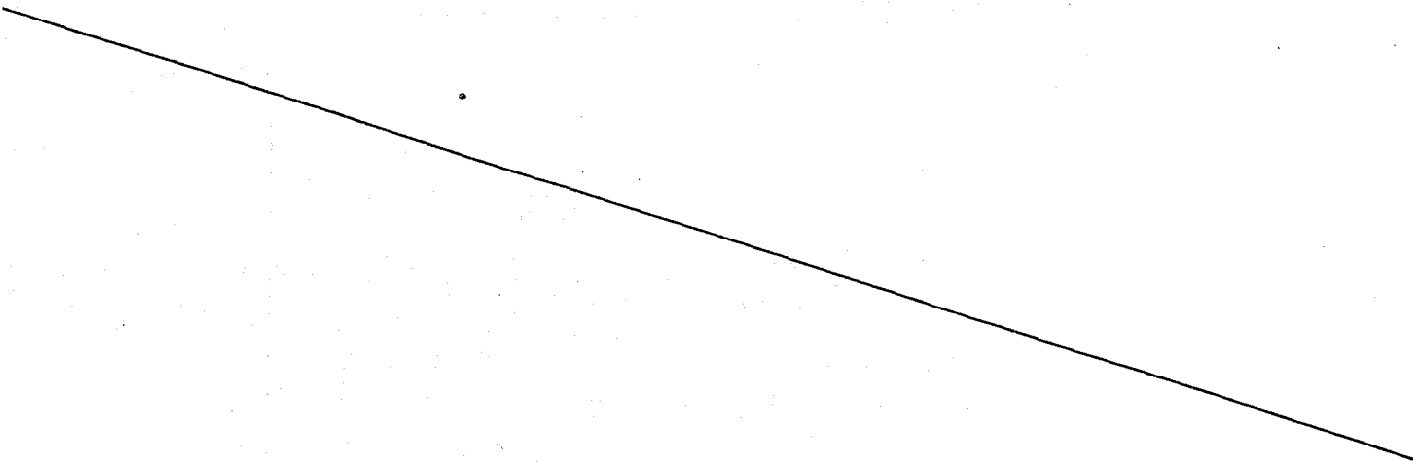
*Agenda:* On March 15, 2002, the committee will hear updates on: (1) Personnel and lot release activities of the Laboratory of Immunobiochemistry (LIB), (2) LIB research programs, (3) particulates in allergen extracts, (4) reduction of possible risk of exposure to transmissible spongiform encephalopathy (TSE) agents in allergen extracts, and (5) the statistical power of clinical studies used to assess bioequivalence of allergen extracts. The committee will discuss: (1) Considerations for the regulation of recombinant allergens for the diagnosis and treatment of allergic disease, and (2) glycerol in allergen extracts.

*Procedure:* On March 15, 2002, from 8 a.m. to 3:15 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 7, 2002. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12 noon, and between 2:45 p.m. and 3:15 pm. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 7, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

*Closed Committee Deliberations:* On March 15, 2002, from approximately 3:15 p.m. to 4:15 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion will be closed to permit discussion of the report of the site visit review of the Laboratory of Immunobiochemistry, in the Division of Bacterial, Parasitic & Allergenic Products, in the Office of Vaccines Research and Review, Center for **Biologics** Evaluation and Research.

Persons attending FDA advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

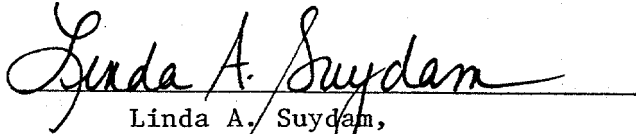
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or **Pearline** Muckelvene at least 7 days in advance of meeting.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 2.22.02  
February 22, 2002.



Linda A. Suydam,  
Senior Associate Commissioner for  
Communications and Constituent Relations.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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